

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

Protocol summary

Study aim

Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

Design

Before and after pilot clinical trial, Phase 3, on 45 patients, without blinding and control group

Settings and conduct

After recording the information of patients admitting to Shohadaye Tajrish Hospital, they complete the form of the number and severity of hot flashes episodes on a daily basis for a week, and at the end of the week, the number and severity of hot flashes episodes as well as the number of days without hot flashes episodes are calculated and considered as baseline values before the intervention. Then, patients use 5 cc of chicory and fumitory herbal products daily, fasting in the morning and at night for 4 weeks, and also complete the the form. After 4 weeks, the effect of the herbal product on the number and severity of hot flashes is analyzed.

Participants/Inclusion and exclusion criteria

Menopause (absence of menstruation during the last 12 months); Complaints of hot flashes; No use of anticoagulant medications; No history of any cardiovascular disease, diabetes, hypertension, neurological disease or cancer; Do not use cupping, acupuncture, medication, especially hormonal drugs, and not treating hot flashes with other methods during the last month; Do not use antidepressants in the last 4 weeks (venlafaxine, bupropion, fluoxetine, paroxetine, citalopram, sertraline); FSH > 40 IU/L; Having the consent to start and continue the study

Intervention groups

A group of chicory and fumitory product consumer

Main outcome variables

Improvement of hot flashes severity in postmenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160722029027N13**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **retrospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

nazari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

Public title

Effects of herbal product of chicory and fumitory on hot flashes in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Menopause (absence of menstruation during the last 12 months) Complaints of hot flashes FSH > 40 IU/L Having the consent to start and continue the study

Exclusion criteria:

History of any cardiovascular disease, diabetes, hypertension, neurological disease, cancer of the breast, ovary, uterus, or hormone-sensitive diseases such as endometriosis or uterine fibroids Use antidepressants in the last 4 weeks (venlafaxine, bupropion, fluoxetine, paroxetine, citalopram, sertraline) Use of anti-anxiety drugs, gabapentin, pregabalin, clonidine, aspirin, vitamin E, omega 3, phytoestrogen supplements and high phytoestrogen diet during the intervention Use of acupuncture and complementary medicine (hypnosis, psychosomatic therapies) during the intervention Use cupping, acupuncture, medication, especially hormonal drugs, and not treating hot flashes with other methods during the last month Use of anticoagulant medications Taking herbal medicine or special diet to treat hot flashes Drug allergy to chicory and fumitory products

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yaman St, Chamran highway, Shahid Beheshti University of Medical Sciences

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Province

Tehran

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1983969411

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.SBMU.MSP.REC.1398.460

Health conditions studied**1****Description of health condition studied**

Menopausal and climacteric symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes**1****Description**

Number and severity of hot flashes episode

Timepoint

Daily

Method of measurement

Recording the number and severity of hot flashes episodes (Green Climacteric Scale) by patient

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Use of 5 cc of chicory and fumitory products, in the morning and at night, for 4 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Tajrish hospital

Full name of responsible person

Dr. Leila Nazari

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Tajrish square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Nazari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

General patient data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available